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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/010,020	12/05/2001	Gary B. Gordon	10002431-4	5593

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AGILENT TECHNOLOGIES, INC.
Legal Department, DL429
Intellectual Property Administration
P. O. Box 7599
Loveland, CO 80537-0599

EXAMINER

FORMAN, BETTY J

ART UNIT	PAPER NUMBER
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1634

DATE MAILED: 07/20/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/010,020	Applicant(s) GORDON, GARY B.	
	Examiner BJ Forman	Art Unit 1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 May 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 8, 10, 11, 14 and 15 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 8, 10, 11, 14 and 15 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 5 May 2005 has been entered.

Status of the Claims

2. This action is in response to papers filed 5 May 2005 in which claim 8 was amended. The amendments have been thoroughly reviewed and entered.

The previous rejections in the Office Action dated 2 December 2004 over Gordon et al are withdrawn in view of Applicant's arguments. The previous rejections over Robbins et al are maintained. Applicant's arguments have been thoroughly reviewed and are discussed below.

Claims 8, 10-11 and 14-15 are under prosecution.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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4. Claims 8, 11-12, 14-15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 8, 11-12, 14-15 are indefinite in Claim 8, line 10 because it is unclear whether the recitation "that is more orthogonal...." modifies the agitation axis or centrifugation axis. It is suggested that the claim be amended to clarify e.g. replace "that" with "wherein said agitation axis".

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 8, 10-11 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Robbins et al (U.S. Patent No. 5,380,662, issued 10 January 1995).

Regarding Claim 8, Robbins et al teach a reaction cell (bottle) having a hybridization array (nucleic acid blots on a membrane, Column 3, line 7-10) so that some interior volume is partially occupied by a sample liquid and partially occupied by gas (Fig. 4) wherein centrifugation (via rotational force, column 3, lines 43-47) of the sample liquid is by rotating the reaction cell whereby agitation of the sample during the centrifugation moves the sample relative to the array (Column 3, lines 4-57 and Abstract).

Robbins et al further teach their device is primarily used for nucleic acid hybridization (Column 3, lines 7-8) but they do not specifically teach the claimed steps of introducing a

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liquid sample into the reaction cell. However, the primary use being hybridization clearly suggest doing so. It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to apply the device of Robbins et al to hybridization wherein a sample is introduced into their hybridization bottle based on their suggestion of using their device for hybridization.

Robbins et al teach applying rotation force via centrifugation i.e. rotation about an axis (Column 3, lines 43-47). While they do not specifically teach a force in excess of 1G, the claimed force is inherent in the rotational "force" of Robbins. Alternatively, it would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to modify rotational force of Robbins et al to obtain a force in excess of 1G based on desired results.

Robbins et al further teach the agitation involves rotating the cell about an agitation axis wherein the angle of agitation "offset" from the centrifugation angle (Column 7, lines 54-62).

Regarding Claims 10-11, Robbins et al specifically teach adjustment of the agitation based desired application (Column 7, line 54-Column 8, line 22). While they do not specifically teach changing direction of rotation or relative rates of rotation and agitation their teaching of adjustability clearly suggests doing so. It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to modify change the direction and/or rates of rotation and agitation based on the suggestion of Robbins to do so (Column 7, line 54-Column 8, line 22).

Regarding Claim 15, Robbins et al illustrate the liquid occupies less than half of the volume (Fig. 4) and they clearly suggest so wherein they teach the agitation provides uniform coating and wetting of the membrane while using minimum amount of solution (Column 3, lines 23-30).

Response to arguments

7. Applicant asserts that Robbins teaches a single axis of rotation in contrast to the instantly claimed two distinct axis of rotation. The argument has been considered but is not found persuasive because, as stated above, Robbins clearly teaches "offset" agitation (Column 7, lines 54-62 and Fig. 4). While the instant claims require two axis i.e. centrifugation and agitation, the instant claims only require a single rotational axis i.e. centrifugation. The axis of agitation is not limited to a rotational axis. Figure 1 illustrates the hybridization chamber mounted on two opposing and offset wheels. Because the wheels are offset, the chamber rocks back and forth and the chamber travels about the centrifugal axis. The back and forth rocking is about an axis (not illustrate, but clearly present) tangential to the chamber and approximately perpendicular to the centrifugal force directed outward from the centrifugal axis (41).

Applicant argues that the rotation of Robbins does not inherently provide forces in excess of 1G as claimed. Applicant further argues that Robbins does not teach urging or agitating the sample against the array. The argument has been considered but is not found persuasive because as stated above, Robbins et al specifically teach applying rotation force via centrifugation i.e. rotation about an axis (Column 3, lines 43-47). Furthermore, they teach "sloshing" within the bottle (Column 8, line 5). While they do not specifically teach a force in excess of 1G or the term "urging", the claimed force is inherent or an obvious application of the rotational "force" and "sloshing" of Robbins.

Applicant asserts that the rotisserie rotation of Robbins suggests a centrifugal force of less than 1G, but not greater than 1 G as claimed. Applicant's assertion is noted but is not supported by factual evidence of such. Therefore the arguments are deemed non-supported arguments of counsel.

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8. Claim 14 is rejected under 35 U.S.C. 103(a) as being unpatentable over Robbins et al (U.S. Patent No. 5,380,662, issued 10 January 1995) in view of Trulson et al (U.S. Patent No. 5,834,758, issued 10 November 1998).

Regarding Claim 14, Robbins et al teach a reaction cell (bottle) having a hybridization array (nucleic acid bolts on a membrane, Column 3, line 7-10) so that some interior volume is partially occupied by a sample liquid and partially occupied by gas (Fig. 4) wherein centrifugation (via rotational force, column 3, lines 43-47) of the sample liquid is by rotating the reaction cell whereby agitation of the sample during the centrifugation moves the sample relative to the array (Column 3, lines 4-57 and Abstract). Robbins et al do not teach removal of the sample.

Trulson et al teach a similar array hybridization method comprising introducing a sample liquid into a reaction cell so that some of the interior volume is partially occupied by sample liquid and partially occupied by gas (N₂ bubbles) and agitating said sample liquid in the reaction cell during centrifugation so that said sample liquid moves relative to the array (Column 9, line 27-50 and Column 14, lines 12-42) and further comprising removing sample liquid from the reaction cell wherein removing the liquid involves rotating (agitating using injected N₂) to force fluid away from the array (Column 14, lines 12-60). Trulson et al further teach the agitation system effectively moves fluids into and out of the reaction cell (Column 9, lines 37-40 and Column 14, lines 36-40).

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to apply the sample removal of Trulson et al to the hybridization device of Robbins for the expected benefit of efficient fluid movement into and out of the reaction cell as illustrated by Trulson et al (Column 9, lines 37-40 and Column 14, lines 36-40).

Response

9. Applicant has provided no specific arguments traversing the above rejection. The rejection is maintained.

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Conclusion

10. No claim is allowed.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to BJ Forman whose telephone number is (571) 272-0741. The examiner can normally be reached on 6:00 TO 3:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones can be reached on (571) 272-0745. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

BJ Forman, Ph.D.
Primary Examiner
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July 15, 2005